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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,420	07/23/2003	Nancy Auestad	6960USP1	9175

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ROSS PRODUCTS DIVISION OF ABBOTT LABORATORIES
DEPARTMENT 108140-DS/1
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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,420	AUESTAD ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-29 are presented for examination.

Applicant is notified that the finality of the previous Office Action dated September 29, 2005 is hereby withdrawn and prosecution of the present application has been reopened.

Claims 1-29 remain pending and claims 5-6, 10-11, 16-17, 22-23, 26 and 29 were amended via the amendment filed under 37 C.F.R. 1.116 dated October 13, 2005. An advisory action dated November 7, 2005 was mailed to notify Applicant that the amendment had been entered into the record. Applicant's subsequent submission of the Appeal Brief filed January 30, 2006 was received and entered into the application. Accordingly, the finality of the previous Office Action dated September 29, 2005 has been withdrawn and prosecution has been reopened.

Status of Rejections under 35 U.S.C. 102 and 103 Proposed for Appeal

Applicant's Appeal Brief filed January 30, 2006 appealed the rejections made under 35 U.S.C. 102(a) and 35 U.S.C. 103(a) over the reference to Jandacek et al. (WO 02/00042; 2002). Applicant's remarks regarding the improper conclusion that the reference teaches the use triacylglycerol esters as satiety agents have been found to be persuasive. Applicant states, "Jandacek fails to disclose the effective use of triacylglyceryl esters of long-chain n-3 polyunsaturated fatty acids as satiety agents. Jandacek repeatedly specifies the use of non-glycerol esters as satiety agents (see Jandacek at p.4, line 10; p.5, lines 4, 11-12, 24 and 26; p.7, line 3)." (see page 4 of Appeal Brief)

Such remarks have been found persuasive upon further reconsideration of the reference to Jandacek et al. The reference does not teach, fairly suggest or provide adequate guidance to one

of ordinary skill in the art to employ a triacylglycerol ester formulation of the disclosed fatty acids. In fact, Applicant's assertion that Jandacek et al. teaches away from the use of triacylglycerol esters is persuasive. The final rejection of claims 1-29 over Jandacek et al. has been found to be in error and has been properly withdrawn.

However, upon further reconsideration of the claims, new grounds of rejection are set forth below.

Claim Rejection - 35 USC § 112, Second Paragraph (New Ground of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The MPEP sets forth the following at §2173: "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what Applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph, with respect to the claimed invention." (See MPEP §2173).

The term "modulating" in phrase "for modulating the appetite of a mammal" as recited in present claim 7 is a term that renders the claims indefinite. The expression "modulation" is not

defined by the claims to properly delineate whether Applicant intends the composition to have bioactivity sufficient to increase the appetite of a mammal or whether it has bioactivity sufficient to decrease the appetite of a mammal.

Regarding the term "modulation", the present specification fails to provide a limiting definition for the term. Given its broadest, most reasonable interpretation, the term "modulate" encompasses the increase (i.e., activation, enhancement or stimulation) or decrease (i.e., suppression, inhibition, or depression) of a reaction or activity. In the absence of any limiting definition, Applicant has conceivably claimed both increasing the appetite and decreasing the appetite of a mammal. It is unclear from both the claims and the corresponding disclosure how a single compound or composition is capable of exerting two opposing effects when administered to the same host (i.e., either activation **or** inhibition of appetite).

For these reasons, the claims as written do not reasonably apprise the skilled artisan of the metes and bounds of the subject matter for which Applicant seeks protection. Claims 7-11 fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 102 (New Grounds of Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I Claims 1-4, 12-15, 18-21, 24-25 and 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Cotter et al. (U.S. Patent No. 4,920,098; 1990).

Cotter et al. teaches methods of administering an enteral (col.3, lines 54-55; see present claims 1, 12, 18, 24 and 27) nutritional therapy to an individual under treatment for or at risk of atherosclerotic, vascular, cardiovascular and/or thrombotic diseases (col.2, lines 30-36; see present claims 1, 12, 18, 24 and 27), comprising a fat source (col.2, lines 37-39) in an amount of 10-40% by weight of the caloric source of the composition (col.3, lines 13-15; see present claims 1, 12, 18, 24 and 27), comprised of long chain triglycerides and medium chain fatty acids (col.2, lines 49-51; see present claims 1, 12, 18, 24 and 27), wherein the long chain triglycerides are preferably marine oils containing large amounts of docosahexaenoic acid (DHA; col.2, lines 56-61; see present claims 2-3, 13-14, 19-20, 25 and 28), and a carbohydrate, protein and electrolyte source (col.2, lines 37-39).

The present claims (see claims 4, 9, 12 and 21) are drawn to the embodiment wherein the n-3 PUFA is administered during a growth phase prior to or in conjunction with an appetite-impacting stimulus. Because the human body is a dynamic entity and is constantly in a state of growth and change, throughout infancy, adolescence or adulthood, Cotter et al. properly anticipates this claim limitation because growth of the human body would be necessarily present at any time the composition was administered. In addition, because the human body constantly requires regular feeding for proper nutrition and health, the administration of the composition of Cotter et al. would necessarily be administered prior to or at the time of an "appetite-impacting stimulus", regardless of when the composition was administered.

Cotter et al. expressly teaches the identical steps to those presently claimed, i.e., the

enteral administration of an amount of the long-chain n-3 polyunsaturated fatty acid, docosahexaenoic acid, in the form of a triglyceride (i.e., triacylglycerol) to a human patient (i.e., mammal). For this reason, the decrease or modulation in the appetite of the mammal (see present claim 1); the antagonism of the CB1 cannabinoid receptor (see present claim 12); the decrease in the incidence of obesity (see present claim 18); the increase in serum leptin levels (see present claim 24) and the reduction in appetite (see present claim 27) are each the necessary end results of the enteral administration of a therapeutic composition comprising docosahexaenoic acid. The claiming of a new use, new function or unknown property that is necessarily present in the prior art does not necessarily make the claim patentable. Please reference MPEP §2112. It is irrelevant that the prior art observer did not recognize the property or function of the disputed claims; if the prior art necessarily possesses that characteristic, it properly anticipates.

II Claims 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Mazer et al. (U.S. Patent No. 6,200,624; March 2001).

Mazer et al. teaches enteral formulas comprising fat in the form of egg-derived triglycerides (col.7, lines 4-20; see present claim 7), such as arachidonic acid (col.4, line 13; see present claim 8) and docosahexaenoic acid (col.4, line 16; see present claim 8), in combination with a protein source and a carbohydrate source (col.4, lines 5-6), which are administered to humans or animals in the form of a pill or capsule for nutritional supplementation (col.17, lines 32-37; see present claim 7).

Present claim 9 is drawn to the embodiment wherein the n-3 PUFA is administered during a growth phase prior to or in conjunction with an appetite-impacting stimulus. Because the human body is a dynamic entity and is constantly in a state of growth and change, throughout infancy, adolescence or adulthood, Mazer et al. properly anticipates this claim limitation because growth of the human body would be necessarily present at any time the composition was administered. In addition, because the human body constantly requires regular feeding for proper nutrition and health, the administration of the composition of Mazer et al. would necessarily be administered prior to or at the time of an "appetite-impacting stimulus", regardless of when the composition was administered.

Mazer et al. expressly teaches the identical steps to those presently claimed, i.e., the enteral administration of an amount of the long-chain n-3 polyunsaturated fatty acid, docosahexaenoic acid, and the n-6 polyunsaturated fatty acid arachidonic acid in the form of a triglyceride (i.e., triacylglycerol) to a human patient (i.e., mammal). For this reason, the modulation in appetite of the mammal (see present claim 1) is the necessary end result of the enteral administration of a therapeutic composition comprising docosahexaenoic acid and arachidonic acid. The claiming of a new use, new function or unknown property that is necessarily present in the prior art does not necessarily make the claim patentable. Please reference MPEP §2112. It is irrelevant that the prior art observer did not recognize the property or function of the disputed claims; if the prior art necessarily possesses that characteristic, it properly anticipates.

Claim Rejections - 35 USC § 103 (New Ground of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotter et al. (U.S. Patent No. 4,920,098; 1990) in view of Mazer et al. (U.S. Patent No. 6,200,624; March 2001) and Jandacek et al. (WO 02/00042; 2002).

Cotter et al. teaches methods of administering an enteral (col.3, lines 54-55; see present claims 1, 12, 18, 24 and 27) nutritional therapy to an individual under treatment for or at risk of atherosclerotic, vascular, cardiovascular and/or thrombotic diseases (col.2, lines 30-36; see present claims 1, 12, 18, 24 and 27), comprising a fat source (col.2, lines 37-39) in an amount of 10-40% by weight of the caloric source of the composition (col.3, lines 13-15; see present claims 1, 12, 18, 24 and 27), comprised of long chain triglycerides and medium chain fatty acids (col.2,

lines 49-51; see present claims 1, 12, 18, 24 and 27), wherein the long chain triglycerides are preferably marine oils containing large amounts of docosahexaenoic acid (DHA; col.2, lines 56-61; see present claims 2-3, 13-14, 19-20, 25 and 28), and a carbohydrate, protein and electrolyte source (col.2, lines 37-39).

Mazer et al. teaches enteral formulas comprising fat in the form of egg-derived triglycerides (col.7, lines 4-20; see present claim 7); such as arachidonic acid (col.4, line 13; see present claim 8) and docosahexaenoic acid (col.4, line 16; see present claim 8), in combination with a protein source and a carbohydrate source (col.4, lines 5-6), which are administered to humans or animals in the form of a pill or capsule for nutritional supplementation (col.17, lines 32-37; see present claim 7).

The differences between the Cotter et al. reference or the Mazer et al. reference and the presently claimed subject matter lie in that the reference fails to teach the presently claimed dosage amounts of 8-396 mg/kg body weight for infants (see present claims 5, 10, 16 or 22) or 84-15,832 mg for children or adults (see present claims 6, 11, 17, 23, 26 or 29).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because the determination of the optimum dosage regimen to modulate appetite, antagonize CB1 cannabinoid receptors or increase serum leptin levels with the presently claimed active agent (i.e., docosahexaenoic acid) would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, including, but not limited to, the age, weight, sex, diet and medical condition of the

patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered a part of a drug combination. Thus, the dosage regimen that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, or evidence of the criticality of the claimed dosage amounts, the currently claimed specific dosage amounts are not seen to be inconsistent with those that would have been determined by the skilled artisan through routine experimentation.

Here, Jandacek et al. is cited to demonstrate that the long-chain n-3 polyunsaturated fatty acid docosahexaenoic acid was known in the art to be administered in an amount of 0.01 g/kg body weight to about 10.0 g/kg body weight (please see page 7, lines 9-13 and page 6, line 33), which for an average 70 kg adult human, would constitute a dosage amount of 0.7-700 g, or 700 mg-700,000 mg, which overlaps the dosage amounts presently claimed. In light of such, it is clear that the art recognized the administration of long chain n-3 polyunsaturated fatty acids in amounts encompassing or overlapping those amounts presently claimed and, thus, the use of long-chain n-3 polyunsaturated fatty acids in amounts such as those presently claimed would have naturally commended themselves, and would have been *prima facie* obvious, to one of ordinary skill in the art.

In addition, the skilled artisan would have been further motivated to combine the teachings of Cotter et al. and Mazer et al. because each teaches the use of n-3 polyunsaturated fatty acids, such as docosahexaenoic, optionally in combination with arachidonic acid, for nutritional supplementation of a human subject. Thus, it would have been *prima facie* obvious to

one of ordinary skill in the art to merge the teachings of each of the references since each is directed to the resolution of the same issue, i.e., nutritional supplementation, and, thus, it would have been reasonably expected that the methods of treatment disclosed by Cotter et al. would have been amenable to combination with those methods taught by Mazer et al. because each individual reference teaches the same components for the same therapeutic objective.

Applicant's attention is drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." While the presently claimed amounts are drawn to mg or mg/kg body weight amounts, such a motivation is nonetheless relevant.

Conclusion

Rejection of claims 1-29 is deemed proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

April 15, 2006

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